III. Rejection of Claims 1, 2,10, 12, 36, 37 and 43-45 under 35 U.S.C. 103(a)

The Office Action rejected claims 1, 2, 10, 12, 36, 37 and 43-45 as being unpatentable over Borodic U.S. Patent 5,183,462 ("Borodic") with Vadoud-Seyedi et al. ("Vadoud") and Slate et al. U.S. Patent 6,645,169 ("Slate"). Applicant respectfully traverses the rejection.

Solely to facilitate prosecution, Applicant has amended independent claims 1, 36 and 45 in order to recite use of botulinum toxin in powder form that is compatible with the use of needleless injectors described in the present specification. As disclosed in the present specification the various Powderject Injectors, that is, injectors that inject powders and not liquids, posses and confer various advantages for patients and users. For example and as disclosed on page 24, lines 20-30 of the specification, the use of these types of needleless injectors (examples of which are provided on page 23, lines 22-24 of the specification) improves clinical safety by eliminating the risk of infection from potential splash back of bodily fluids from liquid jet injectors, thereby avoiding the possibilities of cross-contamination of blood-borne pathogens such as HIV and hepatitis B. Additionally, the needleless injector of the present invention, such as the Powderject System, also offers an optimal and specific delivery of drug particles (here botulinum toxin) with little pain or skin damage, such as bruising or bleeding.

Independent claims 1, 36 and 45, as well as new independent claim 46, are all limited to the administration of botulinum toxin in powdered form.

A review of Borodic shows that there is no disclosure or teaching relating to the use of botulinum toxin in powder form, nor how one would administer the powder. Indeed, the only route of administration disclosed in Borodic for the cosmetic use of botulinum toxin is via a standard teflon-coated needle (col. 1,

lines 44-46). Borodic's disclosure is limited to the reconstituted use of lyophilized toxin, that is, administration of a liquid solution. Thus, Borodic teaches away from the presently amended claims and methods of administration of botulinum toxin.

Vadoud does not remedy these deficiencies of Borodic. Vadoud discloses the use of a Dermojet apparatus that injects a *liquid solution* of botulinum toxin into feet to treat plantar hyperhydrosis. Vadoud also teaches away from the presently claimed invention, as a Dermojet is limited to the administration of *"all types of liquid"* as stated on the Dermojet website (Exhibit A, attached). Vadoud does not disclose the use of botulinum toxin in powder form, nor does it disclose or suggest apparatus that can be used for such novel administration. In fact, the Dermojet is a liquid jet injector, which is the type of injector that the present specification distinguishes the claimed powdered method of delivery from (page 24, lines 14-30 of the instant specification).

Slate also does not remedy the deficiencies of Borodic or Vadoud. Slate simply discloses a method for injecting a *fluid medicament* into a patient (first sentence of abstract, col. 2 lines 51-52, col. 3 line 9). Thus Slate also teaches away from the presently claimed invention, where administration of botulinum toxin in powdered form to treat wrinkles and brow furrows is positively recited. There is *no* disclosure regarding the injection of powdered forms of medicaments in Slate, only fluids.

Thus, Borodic, Vadoud and Slate, taken alone or in any combination, fail to disclose or suggest a method for administering botulinum toxin in powder form using a needleless syringe to reduce a wrinkles (claim 1, 45) or brow furrows (claim 36), or to a subdermal muscle tissue in proximity to the wrinkle (claim 45).

Clearly, the liquid administration devices of Borodic (a syringe) and of Vadoud (Dermajet device) cannot be used to administer a solid, such as a powder. Therefore, the disclosures of Borodic and of Vadoud teach away form administration of a powdered (solid) botulinum toxin. Clearly, due to the differing properties of a liquid and a powder, a powder being a solid cannot be administered using a device configured for administered of an easily flowing liquid. Significantly, a reference which teaches away from a claimed invention cannot be used to support an obviousness rejection. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) ("...the district court erred in...disregarding disclosures in the references that diverge from and teach away from the invention at hand." 220 USPQ at 311) (copy attached as Exhibit B).

Dependent claims 2, 10, 12, 37, 43 and 44 recite various features that further define the present invention and are also allowable over the combination of Borodic, Vadoud and Slate.

For these reasons, the rejection should be withdrawn.

IV. Rejection of Claims 3, 4, 38 and 39 under 35 U.S.C. 103(a)

The Office Action rejected claims 3, 4, 38 and 39 as being unpatentable over Borodic in view of Vadoud and Slate and in further view of McCabe et al. U.S. Patent 5,525,510 ("McCabe"). Applicant respectfully traverses the rejection.

As discussed above, the combination of Borodic, Slate, Vadoud do not in any combination teach or suggest administering botulinum toxin in powdered form to treat wrinkles or brow furrows. In fact, the disclosures of Borodic and Vadoud and Slate taken alone or in combination teach away from the presently claimed invention, as they are all directed to the administration and use of botulinum toxin in solution/liquid form, the apparatuses described in each of the references described and limited as such.

McCabe does not offer a remedy for the deficiencies of the disclosures found in Borodic, Slate, Vadoud taken alone or in combination. McCabe is directed to the use of a "gene gun capable of producing and directing either a continuous flow of DNA coated carrier particles toward relatively large areas of a target organism" (Summary of Invention col. 3, lines 35-38). There is no disclosure in McCabe related to the use of botulinum toxin in a powder form, nor is there any disclosure that suggests the use of such an apparatus to treat wrinkles or brow lines. The use of carriers coated with botulinum toxin in powdered form is not disclosed or suggested by any combination of the cited references.

Clearly, the liquid administration devices of Borodic (a syringe) and of Vadoud (Dermajet device) cannot be used to administer a solid, such as a powder. Therefore, the disclosures of Borodic and of Vadoud teach away form administration of a powdered (solid) botulinum toxin. Clearly, due to the differing properties of a liquid and a powder, a powder being a solid cannot be

administered using a device configured for administered of an easily flowing liquid. Significantly, a reference which teaches away from a claimed invention cannot be used to support an obviousness rejection. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) ("...the district court erred in...disregarding disclosures in the references that diverge from and teach away from the invention at hand." 220 USPQ at 311) (copy attached as Exhibit B).

Thus the rejection should be withdrawn.

V. New Claims 46 and 47

New claims 46 and 47 are directed to a method for treating a wrinkle on a human face. In new independent claim 46, a wrinkle reducing amount of powdered botulinum toxin is administered to subdermal muscle tissue in proximity to the wrinkle using a needleless syringe. The syringe is connected to or connectable to means for producing a supersonic gas flow and has a pressure sufficient to deliver the powdered botulinum toxin to the subdermal muscle tissue associated with the wrinkle to reduce a muscle contraction of the muscle tissue, thereby reducing the wrinkle. Dependent claim 47 specifies that the means for producing a supersonic gas flow is a burst of helium. Support for these new claims is detailed in Section II of this submission.

VI. Conclusion

All issues raised in the Office Action have been addressed. Examination and allowance of claims 1-4, 10, 12, 36-39, and 43-47 is requested.

Respectfully submitted,

Date: September 6, 2006

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Registration Number 52,061

Enclosures: Exhibit A: Dermojet WebPages" (3 pages)
Exhibit B: *W.L. Gore & Associates, Inc. v. Garlock, Inc.*

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this response and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **September 7, 2006** in an envelope as "Express Mail Post Office to Addressee" Mailing Label number **EV763326246US** addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson
Name of person mailing paper

Date: SEPTEMBER 7, 2006

Signature of person signing paper